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Bwrdd Iechyd Prifysgol
Caerdydd a'r Fro
Cardiff and Vale
University Health Board

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NEW PROCEDURES POLICY

Policy Statement

Medical advances are essential and should be encouraged, but patient safety is paramount. History has demonstrated that harm may follow the unregulated introduction of new procedures. Health Boards and Trusts have been made responsible for the prudent introduction of clinical innovations.

The Department of Health issued a Health Service Circular (HSC2003/011) explaining that medical practitioners planning to undertake new interventional procedures (except in emergencies or when the procedure is being used only within a protocol approved by a Research Ethics Committee) must now seek approval according to the policy – and ideally from a relevant Committee before doing so.

This local policy is in line with requirements laid down by the National Institute for Health and Care Excellence (NICE) in the Interventional Procedures (IP) Programme.

NICE define an interventional procedure as: 'A procedure used for diagnosis or treatment that involves incision, puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy.'¹ (p39)

NICE guidance stipulates that to fall within the remit of the Interventional Procedure (IP) Programme, a notified interventional procedure must:

- Involve an incision or a puncture or entry into a body cavity, or the use of ionising, electromagnetic or acoustic energy
- Be available within the NHS or be about to be used for the first time in the NHS, outside formal research
- Be either not yet generally considered standard clinical practice, or a standard clinical procedure, the safety or efficacy of which has been called into question by new information.

Procedures should be notified to NICE if:

- They are entirely novel, with an unknown or uncertain efficacy and/or safety profile; or
- They are a variation of an established procedure which is likely to have a different efficacy and/or safety profile from that of the established procedure.

NICE considers an interventional procedure to be "new" if a fully trained clinician is considering the use of a procedure/technique for the first time in the NHS outside Research Ethics Committee approved protocol. Performing an established procedure using a new device would not usually fall within the remit of the policy unless the use of the new device appears to alter the safety and efficacy of the procedure.

The term clinician includes any health practitioner engaged in the care of a patient.

Document Title: New Procedure Policy	2 of 5	Approval Date: 16.Jun 2015
Reference Number: UHB 274		Review Date: 16 Jun 2018
Version Number: 1		Date of Publication: 23 Oct 2015

All new or personally developed clinical procedures, major modifications of established practice, procedures new to the UHB and procedures with NICE Guidance must be agreed before introduction.

'The IP Programme assesses the efficacy and safety of interventional procedures, with the aim of protecting patients and helping clinicians, healthcare organisations and the NHS to introduce procedures appropriately. By reviewing evidence, consulting widely, facilitating data collection and analysis, and providing guidance on the efficacy and safety of interventions, the Programme enables clinical innovation to be conducted responsibly. No interventional procedure is entirely free from risk; the Programme gauges the extent of risks and benefits and makes recommendations in terms of their implications'. ^{1 (p5)}

The key aims of this policy are:

- To protect patients by ensuring that there is a consistent approach to the introduction of new clinical procedures within the UHB.
- To ensure competence, consent, and reporting arrangements for current practice wherever there are issues of patient safety.
- To assist staff with identifying their roles and responsibilities in ensuring that appropriate actions are taken by individuals, groups and committees with regard to ensuring patient safety, clinical effectiveness and best outcome.
- To ensure patients receive the most appropriate interventions available.
- To ensure appropriate commissioning arrangements are made and to manage resources in accordance with NHS Wales Prioritisation Framework.

The New Procedures Policy is primarily aimed at trained clinical staff with professional autonomy to modify practice. It is equally pertinent to all staff with any clinical contact where harm might follow the unregulated development, or adoption of new techniques or procedures.

In practice this policy applies to any circumstance in which any healthcare professional proposes to carry out a clinical procedure with which they are unfamiliar and which, by its nature, may expose the patient to risk.

The policy is potentially wide reaching and is intended to include clinical competence in all circumstances in addition to new procedures and NICE procedures.

This policy is not intended to affect minor incremental change in clinical practice and, over-reporting to the UHB (and NICE) is encouraged. It does not apply to the introduction of new drugs, which are dealt with separately by the Medicines Management Group.

Policy Commitment

The UHB must be assured that all practitioners are competent in all the activities that they undertake and that appropriate funding and other resources are agreed in advance. As part of

Document Title: New Procedure Policy	3 of 5	Approval Date: 16.Jun 2015
Reference Number: UHB 274		Review Date: 16 Jun 2018
Version Number: 1		Date of Publication: 23 Oct 2015

this requirement, there is a responsibility to ensure that all new clinical techniques and procedures that are introduced into clinical practice are safe and effective, and in particular, in line with, and in support of NICE Interventional Procedures requirements and NICE Medical Technologies requirements.

No procedure is completely 'safe'; all interventions are associated with risks of one kind or another. Decisions relating to safety need to be made in the context of the natural history of the condition being treated or investigated, and the alternative treatments available.

Process for requesting the introduction of a new procedure

This is described in the New Procedures Procedure. Local decision makers should review NICE and other relevant guidance to ascertain safety and efficacy of the proposed new procedure.

Responsibilities

All clinical and managerial staff are responsible for ensuring that patients are treated in accordance with this policy.

Supporting Procedures and Written Control Documents

This Policy and the New Procedures Procedure [*insert document title if only one otherwise say 'supporting procedures'*] describe the following with regard to introducing new procedures.

In order to manage demand for NHS services the *All Wales Prioritisation Framework* was introduced in December 2011 and provides a clear, rational approach for all Health Boards and the Welsh Health Specialised Services to use when assessing options for resource allocation.

If an intervention does not form part of the routine schedule of UHB services, and is also not listed in the interventions not normally undertaken (INNU) list part 1 (which may include new and experimental treatments yet to be assessed)

(<http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/165527>) requests for it to be undertaken can also be made using the process set out in the *All Wales Policy for Individual Patient Funding Requests*

(<http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/220685>) in clinically exceptional circumstances.

The policy for INNU should be adhered to where the evidence of clinical benefit in relation to harm and/or cost effectiveness is limited to such a degree that undertaking them may be unjustifiable. They are either not normally available on the NHS in Wales, or are available within specified criteria.

The responsibility to inform the UHB and gain agreement before proceeding rests with the individual clinician. The individual clinician has a responsibility to inform the UHB and NICE by submission of the attached form (Appendix 1) of any procedure which might fall into this category.

Other supporting documents are:

List all documents the reader needs to be aware of alongside / in support of this document

Document Title: New Procedure Policy	4 of 5	Approval Date: 16.Jun 2015
Reference Number: UHB 274		Review Date: 16 Jun 2018
Version Number: 1		Date of Publication: 23 Oct 2015

Health Service Circular (HSC2003/011) - Department of Health -
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4064925.pdf

National Institute for Health and Care Excellence (NICE) Interventional Procedures (IP) Programme Methods Guide. <http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/The-interventional-procedures-programme-methods-guide.pdf>

National Institute for Health and Care Excellence (NICE) Interventional Procedures (IP) Programme Process Guide.
<http://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-interventional-procedures/Interventional-procedures-programme-process-guide.pdf>

Interventions not normally undertaken (INNU) list part 1
(<http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/165527>)

All Wales Policy for Individual Patient Funding Requests
(<http://www.cardiffandvaleuhb.wales.nhs.uk/opendoc/220685>)

All Wales Prioritisation Framework - December 2011
([http://www2.nphs.wales.nhs.uk:8080/HealthTopicLeads.nsf/85c50756737f79ac80256f2700534ea3/c997185d64441b3980257bb80049f48d/\\$FILE/Prioritisation%20Framework_Final%2021-12-11.pdf](http://www2.nphs.wales.nhs.uk:8080/HealthTopicLeads.nsf/85c50756737f79ac80256f2700534ea3/c997185d64441b3980257bb80049f48d/$FILE/Prioritisation%20Framework_Final%2021-12-11.pdf)

Scope

This policy applies to all of our staff in all locations including those with honorary contracts.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to be potential for positive and negative impacts depending on the new procedure being implemented – each will have its own EqIA. Key actions have been identified and these can be found in the Procedure for New Procedures.
Health Impact Assessment	A Health Impact Assessment desk top exercise was done and determined that a full assessment is not required for this policy.
Policy Approved by	Quality, Safety and Experience Committee
Group with authority to approve procedures written to explain how this policy will be implemented	Health System Management Board
Accountable Executive or Clinical Board Director	Medical Director

Document Title: New Procedure Policy	5 of 5	Approval Date: 16.Jun 2015
Reference Number: UHB 274		Review Date: 16 Jun 2018
Version Number: 1		Date of Publication: 23 Oct 2015

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Governance Directorate](#).

Summary of reviews/amendments			
Version Number	Date Review Approved	Date Published	Summary of Amendments
1	Date approved by Board/Committee/Sub Committee 16/06/2015	23/10/2015	New Policy
2			